K091261

MAY 12 2009

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510(k) Summary

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Nicholas Condakes Manager, Regulatory Affairs 508-658-7931	or	Lorraine M. Hanley Director, Global Regulatory Affairs 508-658-7945

C. Device Name

Tradename:	To be determined
Common/usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	LJS - Long term intravascular catheter 21 CFR 880.5970, Class II

D. Predicate Device(s)

Common/usual name: Peripherally Inserted Central Catheter (PICC)
Classification Name: LJS- Long term intravascular catheter, 21 CFR 880.5970, Class II
Premarket Notification(s): K070002, K021704

E. Device Description

The proposed PICC has similar technological characteristics as the predicate devices. It is a flexible catheter with proximally located luer lock adapter(s) with a pressure activated safety valve, extension tube(s) and suture wing for catheter securement; available in single and dual lumen configurations (4 Fr SL, 5 Fr SL, 5 Fr DL, 6 Fr DL) and effective (usable) length of 55 cm. The radiopaque catheter is marked with depth indicators along its length. The lumens are differentiated by proximally located colored hubs that indicate lumen size. Maximum power injection flow rates are indicated on the luer adapter(s). The proposed PICC may be provided as a stand alone device or in kits with other legally marketed products as a convenience to the user to accommodate their particular needs.

F. Intended Use

The proposed device is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

G. Performance Data

Performance testing included *in-vitro* testing in accordance with ISO 10555-1 and ISO 10555-3; high pressure injection flow rates; and valve integrity testing; and biocompatibility evaluation in accordance with ISO 10993-1.

H. Substantial Equivalence

Based on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2009

Mr. Nicholas Condakes
Regulatory Affairs Manager
Navilyst Medical, Incorporated
26 Forest Street
Marlborough, Massachusetts 01752

Re: K091261
Trade/Device Name: Undetermined
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 28, 2009
Received: April 29, 2009

Dear Mr. Condakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): _____

Device Name: To be determined

Indications For Use: For short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

Prescription Use __X__ **AND/OR Over-The-Counter Use**____

(21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ABC LCDR Colburn 05/10/2009
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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